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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,767	02/26/2001	David Edwin Thurston	65435-9002	6332

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

14

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/763,767

Applicant(s)
THURSTON et al.

Examiner
Brenda Coleman

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1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 20, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-10, 12, 13, 15-21, 25-27, 29, 32-38, 40, 42, 46-60, and 62-6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13, 15-19, and 47 is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 20, 21, 25-27, 29, 32-38, 40, 42, 46, 48-60, and 62-65 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1, 3-10, 12, 13, 15-21, 25-27, 29, 32-38, 40, 42, 46-60 and 62-65 are pending in the application.

This action is in response to applicants' amendment filed October 20, 2003. Claims 21, 25-27, 34, 38, 42, 50, 56, 60, 62 and 63 have been amended, claims 28, 31, 43, 44 and 61 have been canceled and claim 65 is newly added.

Response to Amendment

Applicants' arguments filed October 20, 2003 have been fully considered with the following effect:

1. With regards to the obviousness-type double patenting rejection as being unpatentable over copending Application No. 09/763,813 in the last office action, the applicants stated that "the examiner has not established as a *prima facie* case of obviousness" and that "the examiner has provided no analysis as to the difference between the inventions claims by the conflicting claims compared to as a claim in the instant application, and so to the reasons why as a person of ordinary skill in the art would have concluded that the invention defined in the claims of the present invention is an obvious variant of the inventions defined in the claims of the copending applications". However, claims 17-19 of copending Application No. 09/763,813 embrace compounds, compositions and method of use of the compounds as claimed herein where at least one of R₆, R₇ and R₈ is an OR moiety and R is a **lower alkyl** group having 1 to 10 carbon atoms, or an **aralkyl** group of up to 12 carbon atoms, whereof the alkyl group optionally contains one or

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more carbon-carbon double or triple bonds, which may form part of a conjugated system, or an **aryl** group of up to 12 carbon atoms; and is optionally substituted by one or more halo, **hydroxy**, **amino** or nitro groups.

Claims 1, 3-7, 20, 21, 25-27, 29, 32-38, 40, 42, 46, 48-56, 60, 63 and 65 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19 of copending Application No. 09/763,813. For reasons of record and stated above.

2. With regards to the 35 U.S.C. § 102 anticipation rejection of claims 50-55 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The instant claims are not described in the applicants priority document and thus are only entitled to benefit of PCT/GB99/02838 filed August 27, 1999 as it is **only completely described** in the international application of which the instant application is a national stage entry under 35 U.S.C. § 371. Note *In re Scheiber* 199 USPQ 782 regarding 112 compliance for benefit under 35 USC 120. Applicants attention is drawn to the definition of R₇ and R₈ where R₇ and R₈ together form group -O-(CH₂)_p-O-, where p is 1 or 2 is not described in the applicants priority documents.

Claims 50-55 are rejected under 35 U.S.C. 102(a) as being anticipated by Gregson et al., Chem. Commun. For reasons of record and stated above.

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3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 1, 6-10, 12, 38, 42, 46 and 60, labeled 11a) of the last office action, which is hereby **withdrawn**.

4. With regards to the 35 USC § 112, first paragraph rejection of claims 1, 3-5, 7-10, 38, 42 and 46 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants' stated that there is support in the specification for the definition of R_2 as $CH=CR^A R^B$ at page 3, lines 24-28 where a preferred compound is that where A is a single bond and R_2 is not $CH=CR^A R^B$. The applicants indicated that by implication R_2 is not $CH=CR^A R^B$. However, this negative limitation is for compounds of formula Ia and does not set forth a statement of utility. The implication that R_2 is $CH=CR^A R^B$ for all other permutation claimed herein are not enabled.

Claims 1, 3-5, 7-10, 38, 42 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such as a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For reasons of record and stated above.

5. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 1, 3, 4, 7-10, 13, 15-21, 25-29, 31-33, 38, 40, 42, 46-49 and 57-60, labeled 11c) of the last office action, which is hereby **withdrawn**.

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6. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 38, 40 and 60-64, labeled 11d) of the last office action, which is hereby **withdrawn**.

7. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claim 42, labeled 11e) of the last office action, which is hereby **withdrawn**.

8. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections of claims 21, 25-28, 31, 34, 43, 44, 50-56 and 60-64, labeled 12a), b), c), d), f), h), i), j), k), l), m), n), o), p), q) and r) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled e) and g) the applicant's amendments and remarks have been fully considered but they are not persuasive.

e) The applicants' stated that the "applicants stated that the amendments to claim 26 obviate the rejections". However, with regards to the rejection of claim 26, i.e. the definition of R_6 , R_7 , R_8 and R_9 where R_6 , R_7 , R_8 and R_9 are substituted on the phenyl by methoxy or ethoxy, this is not so.

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Claim 26 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- g) The applicants' stated that the "applicants stated that the amendments to claim 27 obviate the rejections". However, with regards to the rejection of claim 27, i.e. the definition of R₆, R₇, R₈ and R₉ where R₆, R₇, R₈ and R₉ are substituted on the phenyl by p-MeO, this is not so.

Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

In view of the amendment dated October 20, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is as a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain as a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 56 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such as a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following reasons apply:

- a) The amendment to claim 56 where the claim is directed to two species is not described in the specification with respect to the second specie. A claim drawn to a specific species requires description of that species, evidence that applicants possessed that particular species. Cf *In re Rushig*, 154 USPQ 118; *Fields v. Connover*, 170 USPQ 276, 280; *Watson v. Bersworth*, 116 USPQ 445; *Flynn v. Eardley*, 178 USPQ 288; *Ex parte Westfall*, 223 USPQ 631; *In re Prutton*, 96 USPQ 151; *In re Honn*, 150 USPQ 652; *In re Fried*, 136 USPQ 429. The fact that the species fall within the broader genus is not enough.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is as a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 25, 33, 42 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 25 recites the limitation "one or more carbonyl groups, or one or more ether or thioether groups" in the definition of R₆, R₇ and R₉ where R₆, R₇ and R₉ is an aryl group. There is insufficient antecedent basis for this limitation in the claim.

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- b) Claim 33 recites the limitation "R6 and R9" in the claim. There is insufficient antecedent basis for this limitation in the claim.
- c) Claim 42 is vague and indefinite in that it is not known what is meant by the compounds of formula Ia or Ib where formula Ia and Ib are not shown as the pyrrolobenzodiazepine rings defined in the specification, but rather their open ring equivalents.
- d) Claim 62 recites the limitation "8-amino-1,2,3,11a-tetrahydropyrrolo[2,1-c][1,4]benzodiazepin-5-one" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 42 and 57-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of copending Application No. 10/379,049. Although the conflicting claims are not identical, they are not patentably distinct from each other because the process of preparing the compounds of formulae Ia, Ib, II, III and IV are embraced by the process of copending Application NO. 10/379,049 where R_3 is H; R_2 is H, R, OH, OR, =O or =CH₂.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 38, 50-55 and 64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5 and 10 of copending Application No. 10/021,213. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and method of use of the compounds of formula II are embraced by copending Application No. 10/021,213.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claim Objections

13. Claims 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

14. Claims 13, 15-19, 47 are allowed. None of the prior art of record nor a search in the pertinent art area teaches the compounds, compositions or method of use of the compounds of formula II as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of as a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman

Primary Examiner AU 1624

January 12, 2004